

Serial No. 10/575,502  
Docket No. X-16327

**Amendments to the Drawings**

None

**Remarks/Arguments**

In this Response to Office Action, Claim 1 has been amended to recite a structural cooperative relationship of the guide and follower. It is believed that no new matter has been presented as this amendment is supported by the application text and figures. Thus, Claims 1-5, 8 and 9 are pending in this application. Reconsideration and reexamination of the application in view of the remarks presented herein are respectfully requested.

In the Office Action, Claim 1 was rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. It was asserted that claim 1 recites the broad recitation “a guide disposed on one of said driver and said housing; a follower disposed on the other of said driver and said housing”, and the claim also recites “guide comprises first and second surfaces that define a channel in which said follower is slidable” which is the narrower statement of the range/limitation. It is respectfully submitted that such a characterization of the claim language is not accurate and that no change is required. Specifically, the “broad recitation” requires the claimed guide and follower being on opposite ones of the driver and housing. Thus, if the guide is on the driver then the follower is on the housing, and vice versa. The language cited by the Examiner about the guide comprising first and second surfaces etc. does not specify now a narrowing by which the guide is specifically designated as being disposed on the driver or for that matter the housing. Granted, if it was stated that the first and second surfaces were a part of the driver (or the housing), such would be a narrower statement of the range/limitation. However, such is not the case. The language cited is not inconsistent with or a narrowing of the “broad recitation” and is believed to be entirely appropriate. Thus, it is respectfully submitted that this rejection is traversed.

In the Office Action, Claim 1 was also rejected under 35 USC 112, second paragraph, as being incomplete, as it was asserted that it is not clear how the guide and follower cooperate to promote a user moving the driver. In response, Claim 1 has been amended to recite “wherein said guide and follower comprise a surface abutting relationship to promote a user moving said driver relative to said housing along a travel path that operates the apparatus”. This amendment is believed to further specify consistent with the specification the manner in which the guide and follower cooperate. Thus, it is respectfully submitted that this rejection is overcome.

In the Office Action, it was stated that Claims 1-9 were rejected under 35 USC 103(a) as being unpatentable over US Patent No. 6,221,046 to Burroughs. It was also stated that Claims 1-9

were rejected under 35 USC 102(b) as being anticipated by Burroughs, but it is believed such statement of anticipation was an error, and no further comment on such anticipation rejection is believed required.

In response to the above obviousness rejection, it is respectfully requested that the Examiner reconsider the patentability of Claim 1, especially in view of the amendments which were made in the prior office action response and in view of the following observations.

The presence of the hard stop in the travel path in Burroughs to halt the driver rotation at a maximum dose setting is not disputed. However, that hard stop in the Burroughs design is distinguishable from the guide and follower design and purpose of the claimed invention. Note that Claim 1 requires "wherein along said injecting section of said travel path, said guide comprises first and second surfaces that define a channel in which said follower is slidable, said surfaces during injecting serving as physical stops to prevent rotation of said nut driver by abutment by said follower until an injection is complete," as well as that "wherein along said nut rotating segment of said travel path, said guide comprises third and fourth surfaces that define a channel in which said follower is slidable, said third surface providing a distal barrier during nut rotating that prevents distal plunging of said driver by abutment by said follower until said follower passes from said nut engaging segment to said injecting section." The Burroughs hard stop prevents rotation of the driver during dose setting above the maximum dosage. It is not involved with the injecting step per se, but rather the dose setting or preparation. In contrast, the first and second guide surfaces that define a channel in which said follower is slidable serve as physical stops during injecting. In further contrast, these stops prevent rotation of the nut driver in either direction during injecting. The Burroughs hard stop cited by the Examiner serves to stop rotation in only a single direction.

In addition, the Burroughs hard stop, while able to stop a larger than maximum dose from being set, is not positioned to physically prevent an injection of less than a maximum dose. In contrast, the third surface of the guide claimed in Claim 1 does just that, namely by providing a distal barrier during nut rotating that prevents distal plunging of the driver by abutment by the follower until the follower passes from said nut engaging segment to the injecting section.

Just as it would not seem appropriate to suggest that the hard stop in Burroughs can render obvious every conceivable physical stop in an injection pen, it is submitted that Burroughs does not render obvious the particular "stop configurations" claimed if properly reconsidered by the Examiner.

In view of the foregoing, it is respectfully submitted that Claim 1, as well as Claims 2-5, 8

and 9 that are dependent on Claim 1, are in fact patentable and are in condition for allowance. Thus, it is requested that a timely Notice of Allowance be issued in this case.

If any extension of time or fees are required with this paper, such are hereby petitioned therefor and the Commissioner is hereby authorized to charge any such fees to Deposit Account No. 05-0840.

The Examiner is invited to contact the undersigned with any questions if such would advance the prosecution of the present application.

Respectfully submitted,

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